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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Cranial Navigation System – Standard Cranial Reference Array: For specific combinations an inaccuracy of more than 1 mm might be added to the registration result when exchanging Standard Cranial Reference Arrays
Product Reference:	Standard Cranial Reference Array
Date of Notification:	Aug 3, 2012
Individual Notifying:	Julia Mehltretter, MDR & Vigilance Manager
Brainlab Identifier:	11-12-22.TGE.2
Type of action:	Device component exchange; advice regarding use of device

We are writing to advise you of the following effect Brainlab has internally determined for specific combinations of Standard Cranial Reference Arrays when used for the exchange of unsterile with sterile array in conjunction with the Brainlab Cranial Navigation System.

This Notification letter is to provide you with corrective action information, and to inform you of the actions Brainlab is taking to address this issue.

Effect:
Manufacturing tolerances of the Standard Cranial Reference Array influence the actual position of its marker spheres. The differences between the individual arrays are supposed to be very small, not significantly affecting navigation accuracy when the unsterile array is exchanged with the sterile array during surgery.

However, there are specific pairs of arrays that might add an inaccuracy of more than 1 mm to the registration result during the exchange due to the combination of their tolerance limits. The Appendix lists the potentially affected arrays identified by Brainlab simulations.

This effect could potentially cause an inaccurate display of instruments by the navigation system in the region of interest, compared to the actual patient anatomy. If these inaccuracies are not detected by user verification of navigation accuracy as described in the user manual, this could lead to **serious injury or ineffective treatment of the patient**.

Figure1: Standard Cranial Reference Array

Details:
Reference arrays, e.g. the Standard Cranial Reference Array, allow the navigation system to track the location of the patient's anatomy throughout the procedure.

Usually, two reference arrays are used:

- One for preoperative procedures (patient registration). The reference array used for registration may be unsterile as registration is usually performed in an unsterile environment
- One for intraoperative navigation. The reference array used for navigation must be sterilized before use and attached during draping

After the successful registration of the patient using the Brainlab navigation software it is required to carefully remove the unsterile reference array, drape the patient and then attach the sterile reference array.

With this exchange an inaccuracy of more than 1 mm might be added to the registration result if array pairs with specific combinations of tolerance limits are used.

User Corrective Action:
According to our records you are the owner of one or several of the potentially affected Standard Cranial Reference Arrays.

Therefore please check your Standard Cranial Reference Arrays and do not use reference arrays with one of the serial numbers listed in Appendix A and B.

Please note that for article 41730A REFERENCE CLAMP UNIVERSAL (WITH 2 ARRAYS) two reference arrays bear the same serial number. In this case both reference arrays must no longer be used.

Please remove the according reference arrays from clinical use. You will be provided with a replacement accordingly.

Where you can find the serial number:

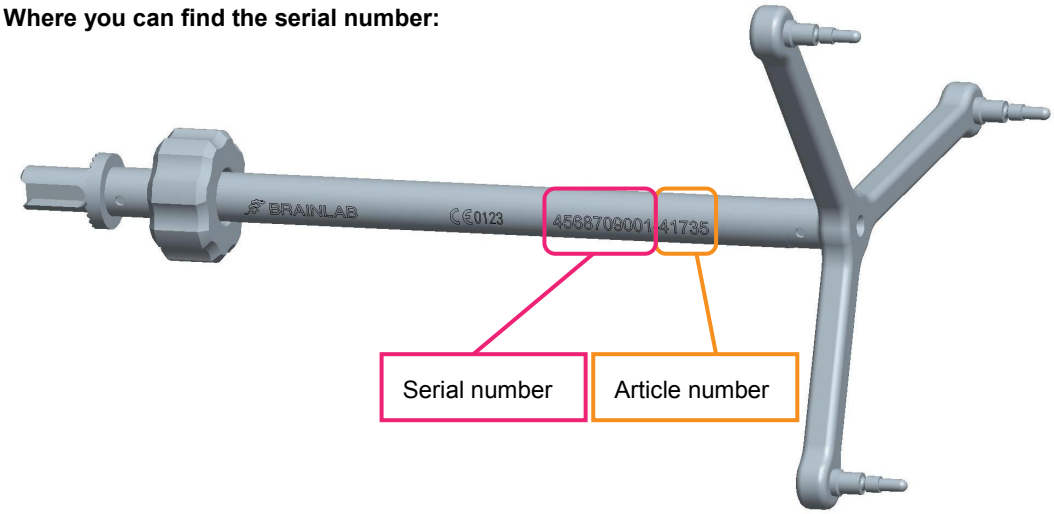

Figure 2 – Where to find the Serial Number on the Standard Cranial Reference Array

In any case, please continue to follow the instructions in the relevant user manuals:

- The Brainlab Cranial/ENT instruments are highly accurate and sensitive medical devices and must be handled with extreme care. If you drop or otherwise damage an instrument, return it immediately to Brainlab for testing. Failure to do so may lead to serious injury to the patient.
- Do not use damaged instruments.
- Do not change the position of the headholder adapter when attaching the sterile reference array. This could result in inaccurate tracking and severe patient injury.
- Verify registration accuracy after exchanging the unsterile reference array for the sterile reference array.
- Do not move a reference array relative to the patient's anatomy during the procedure. Changing the array's position throws off the entire measurement coordinate system, endangering the patient.
- To avoid unintentional movement of the reference array, do not place pressure on it.
- If the position of the reference array changes relative to the patient, a new registration is required.
- A new registration is required if the patient was repositioned after registration.
- Check regularly that the marker spheres remain tightly screwed onto the pins.
- Navigation accuracy critically depends on the condition of the marker spheres used.
- Verify prior to use that the reflective surface of all marker spheres is in good condition, and not peeling.

Brainlab Corrective Action:

1. Existing potentially affected customers who own one or several of the potentially affected Standard Cranial Reference Arrays receive this product notification letter.
2. Brainlab will actively provide revised hardware to improve exchange compatibility to these customers as of October 2012.

Please advise the appropriate personnel working in your department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by
E-mail: support@brainlab.com. Fax Brainlab AG: + 49 89 99 15 68 33
Address: Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

Aug 3, 2012

Kind Regards,

Julia Mehltretter
MDR & Vigilance Manager
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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.

Attachments:
Appendix A – List of affected serial numbers for article 41735
Appendix B – List of affected serial numbers for article 41730A

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Appendix A – List of affected serial numbers for article 41735

Article: 41735 STANDARD CRANIAL REFERENCE ARRAY

Serial numbers	Serial numbers	Serial numbers
1085709026	1120510035	1165711064
1085709029	1120510038	1165711070
1085709030	1120510039	1165711072
1085709035	1120510041	1165711077
1085709040	1120510042	1165711085
1085709042	1120510062	1182611003
1085709044	1136010034	1182611006
1085709045	1136010036	1182611010
1085709054	1136010048	1182611021
1085709056	1136010049	1182611022
1085709057	1136010050	5180108027
1085709058	1136010058	5180108029
1120510002	1136010078	5180108033
1120510004	1136010081	5180108034
1120510012	1136010082	5180108037
1120510013	1136010087	9137-07-002
1120510014	1136010088	9137-07-021
1120510015	1165711003	9137-07-029
1120510017	1165711008	9137-07-036
1120510021	1165711033	9137-07-046
1120510024	1165711041	9137-07-047
1120510032	1165711046	

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Appendix B – List of affected serial numbers for article 41730A

Article: 41730A REFERENCE CLAMP UNIVERSAL (WITH 2 ARRAYS)

Serial numbers	Serial numbers	Serial numbers
1106709012	1153910063	5180008156
1106709019	1153910078	5180008161
1106709023	1153910088	5180008172
1106709026	1153910093	5180008177
1106709029	1153910101	5180008193
1106709040	1153910104	5180008204
1106709067	1153910106	5180008240
1106709068	1153910109	5180008246
1106709069	1153910115	5180008248
1106709097	1153910117	8055-07-006
1106709122	1153910132	8055-07-051
1106709134	1153910133	8055-07-078
1106709135	1153910159	8055-07-087
1106709164	1153910161	8055-07-099
1106709182	1153910164	8055-07-110
1106709183	5180008007	8055-07-111
1106709188	5180008014	8055-07-117
1153910013	5180008020	8055-07-141
1153910016	5180008032	8055-07-156
1153910019	5180008033	8055-07-162
1153910026	5180008043	8055-07-164
1153910027	5180008054	8055-07-168
1153910030	5180008101	8055-07-181
1153910032	5180008106	8055-07-190
1153910033	5180008114	8055-07-205
1153910036	5180008117	8055-07-213
1153910044	5180008136	8055-07-215